5. 510(K) SUMMARY

K123874

December 14, 2012

Owner:

JAN 10 2013

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015

Contact person:

Nanette Hedden
Associate Director, Global Regulatory Affairs
36250 N. Wilson Rd.
Round Lake, IL 60073
Telephone: (224) 270-4871
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DEVICE NAME: IV Administration Sets

Trade Name: Buretrol Solution Sets

Table 5-1
Representative Product Codes for Buretrol Solution Sets

Code Number	Name
1C8441	**Interlink System Buretrol Solution Set**, 77" (2.0 m), 150 mL Burette Ball Valve
2H8862	**Clearlink System Non-DEHP Buretrol Solution Set**, 115" (2.9 m), 150 mL Valveless Burette
3C0128	**Interlink System Buretrol Solution Set**, 105" (2.7 m), 150 mL Burette Drip Chamber Filter Valve **Large Bore 4-Way Stopcock Extension Set**, 34" (87 cm), Vol. 4.6 mL **Minivolume Extension Set**, 2.9" (7 cm), Vol. 0.1 mL

Common Name: Solution Set with Burette Chamber

Classification Name: IV Administration Set (21 CFR 880.5440, Product Code FPA)

PREDICATE DEVICE:

Table 5-2
Previous 510(k)s

Device	Company	Previous 510(k)	Clearance Date
Modified Buretrol Solution Sets	Baxter Healthcare	K984381	February 19, 1999
Burette Set with Air Control Lever – 2C0147	Travenol Laboratories[1]	K780970	July 27, 1978

[1] Travenol Laboratories was renamed Baxter Healthcare in 1988.

DESCRIPTION OF THE DEVICE:

The Buretrol Solution Sets are sterile, single use disposable devices indicated for use in the administration of fluids from a container into the patient's vascular system through a vascular access device. The sets contain a burette chamber which can be used to mix supplementary medication in a measured amount of diluent from the main container. The sets can be adjusted for either metered volume solution administration (intermittent) or continuous solution administration. The sets can be converted from intermittent to continuous administration by closing the air vent at the top of the burette and allowing continuous infusion from the main container. There are different configurations of the burette, based on presence of and differences in valve type.

STATEMENT OF INTENDED USE:

The Buretrol Solution Sets are intended for use in the administration of fluids from a container into the patient's vascular system through a vascular access device.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

The proposed Buretrol Solution Sets are equivalent to Baxter's currently legally marketed Modified Buretrol Solution Sets cleared February 19, 1999 (K984381). The modification to the labeling does not impact the intended use or the fundamental scientific technology of the device. The intended use, basic design, function and the materials for the proposed device are equivalent to the predicate device.

DISCUSSION OF NONCLINICAL TESTS:

Baxter Healthcare Corporation conducts risk analyses and design verification tests based on the results of these analyses. All test results meet their acceptance criteria, and support that the devices are appropriately designed for their intended use.

Performance Data: The following tests were conducted to evaluate the functional performance of the Buretrol Sets:

- Spike Leakage Test Over Time
- Burette Squeeze Test
- Burette Pressure Test
- Burette Scale Legibility
- Roller Clamp Immediate Shut-Off
- Roller Clamp Shut-Off Over Time
- Check Valve Backflow Evaluation
- Regulating Roller Clamp Cold Flow Test
- Regulating Roller Clamp Shut-Off Test
- Air Vent Air Flow Test
- ISO Luer Tests on Male Luer lock

All tests met the acceptance criteria.

Biocompatibility: No new materials of construction are being introduced into these devices as part of this Special 510(k) Premarket Notification. Biocompatibility assessment of the Buretrol Solution Sets has been conducted based on ISO 10993, Biological Evaluation of Medical Devices for prolonged duration, external communicating, indirect blood path and Blue Book Memorandum G95-1 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing," as recommended in the IV Administration sets guidance.

CONCLUSION:

The Buretrol Solution Sets are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 10, 2013

Ms. Nanette Hedden
Associate Director, Global Regulatory Affairs
Baxter Healthcare Corporation
36250 North Wilson Road
ROUND LAKE IL 60073

Re: K123874
Trade/Device Name: Buretrol Solutions Sets
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: December 14, 2012
Received: December 17, 2012

Dear Ms. Hedden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

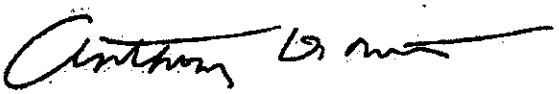
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123874

Device Name: Buretrol Solution Sets

Indication(s) for Use:

The Buretrol Solution Sets are intended for use in the administration of fluids from a container into the patient's vascular system through a vascular access device.

Prescription Use: ☑ AND/OR Over-the-Counter Use: ☐

21 CFR 801 Subpart D 21 CFR Subpart C

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123874